

- (i) a compound as claimed in claim 1; and
- (ii) a compound effective in the treatment of a respiratory, urological or gastrointestinal disease or disorder .

33. (Previously amended) A composition according to claim 32 comprising
- (i) a compound as claimed in claim 1; and
  - (ii) at least one compound chosen from: a  $\beta$ 2 agonist, steroid, antiallergic drug, phosphodiesterase IV inhibitor and a leukotriene D4 (LTD4) antagonist .
34. (Previously Added) A pharmaceutical composition according to claim 26, wherein the composition is an admixture.

### **REMARKS**

#### **I. Status of Claims**

Claims 1-10, 12-20, 23, 24, 26, and 32-34 are pending in the application. Claims 1, 6-9, 18-20, 23 and 24 has been amended and claims 11, 21, 22, 25, 30 and 31 have been cancelled without prejudice to comply with the Examiner's restriction requirement.

In the Office Action, the Examiner made the Restriction Requirement final and provided the status of the claims. However, the Examiner's recitation of the elected Group III narrows the definition of substituent B from what was provided for Group III in the original Restriction Requirement of February 1, 2006. Applicants assume this is a typographical error and have amended the claims to be consistent with the elected group as defined in the Examiner's original restriction requirement.

#### **II. Comments on IDS filed on May 25, 2005**

Applicants respectfully request that the Examiner consider foreign patent document WO 01/04118 as cited in the Information Disclosure Statement submitted May 25, 2005, and indicate it has been considered by initialling the PTO/SB/08. The

document is an English language document and the Examiner has provided no reason for not considering the document.

III. **Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1-10, 12-20, 23-24, 26 and 32-34 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. The Examiner rejected the above listed claims “because of improper use of proviso, which does not clearly point out which compounds or compositions are regarded as the invention, and why certain groups are not included from the generic claim.” Applicants respectfully traverse this rejection.

Applicants respectfully encourage the Examiner to consider M.P.E.P. § 2173.02 which notes that “the essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity.” There is no requirement to state *why* some things are excluded from the claimed invention. Rather, all that is required is that one skilled in the art is able to understand the subject matter.

Undoubtedly, in the claims listed above, the language of the claims with a proviso makes clear what the invention is, including what it is not, and subsequently defines the metes and bounds of the claims. As this satisfies the “test for definiteness” as set out in the M.P.E.P., the Applicants request the withdrawal of this rejection.

The Examiner further rejects claims 32, 33 and 34 under 35 U.S.C. § 112, second paragraph, “as being indefinite for failing to particularly point out and distinctly claim the subject matter.” Applicants respectfully traverse.

In order to meet the requirements of 35 U.S.C. § 112, second paragraph, the claims of the application must define the patentable subject matter with clarity and precision. However, definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the application disclosure, the teachings of prior art, and the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. M.P.E.P. § 2173.02

The Examiner rejects claim 32 on the grounds that the phrase “a compound effective in the treatment of a respiratory, urological or gastrointestinal disease or

disorder” is not defined in the specification. Applicants respectfully submit that there is no special requirement to define each and every term of a claim in the specification.

M.P.E.P. § 2173.02 Moreover, the language of claim 32 is well understood in the art.

In response to the rejection of claim 33, Applicants respectfully submit that one of ordinary skill in the art would understand what is meant by the term “ $\beta$ 2 agonist”, as well as the terms “steroid” and “antiallergic drug,” and would therefore understand the metes and bounds of the presently claimed invention. For example, MedicineNet.com, authors of Webster’s New World Medical Dictionary, defines a  $\beta$ 2 agonist as a bronchodilator medicine which operates by activating  $\beta$ 2 receptors on the muscles surrounding the airways. MedicineNet.com, Definition of Beta-agonist, <http://www.medterms.com/script/main/art.asp?articlekey=24664> (last visited July 25, 2006).

Similarly, in regards to claim 34, Applicants respectfully submit that one of ordinary skill in the art would understand what is meant by the term “admixture,” and would therefore understand the metes and bounds of the presently claimed invention. Merriam-Webster’s Collegiate® Dictionary, for example, defines an admixture as the action of mixing, a product of mixing, a mixture. Merriam-Webster’s Collegiate Dictionary 17 (Merriam-Webster Inc. 11<sup>th</sup> ed. 2004).

As stated in the M.P.E.P., the test for definiteness is whether those skilled in the art would understand what is claimed, when the claim is read in light of the specification. M.P.E.P. § 2173.02. The Examiner has only supported his rejection with conclusory statements and provides no evidence as to why one of skill in the art would not understand what is claimed. Absent some evidence to support these conclusions, Applicants respectfully request that these rejections be withdrawn.

#### IV. **Rejection under 35 U.S.C. § 102**

Claims 1-4, 10, 14, 26, and 32-34 are rejected under 35 U.S.C. § 102(e) as being anticipated by Mehta *et al.*, WO 2002-IB5590 (publication number WO 2004/056767 A1). Applicants respectfully traverse.

The earliest effective prior art date for Mehta *et al.* is December 23, 2002. The current application was filed April 11, 2003, but claims priority to Spanish Patent

Application No. 200200889 filed on April 16, 2002. Claims 1-4, 10, 14, 26, and 32-34 as amended are fully supported in the priority document. By submitting a certified translation of the Spanish language foreign priority document, the Applicants have perfected the foreign priority pursuant to 35 § § 119 (c), 365 (b) and 365 (c). As such, Mehta *et al.* is now unavailable as prior art. Thus, the Applicants request the withdrawal of these rejections.

**Conclusion**

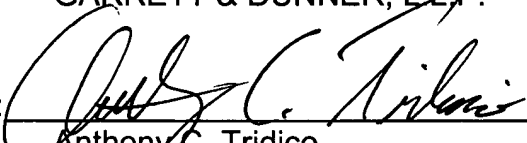
Reconsideration and reexamination of this application is respectfully requested. In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is now in condition for allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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